

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/928,139	08/10/01	LANGSTON M	GJE-136D1

023557 HM12/0928
SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
2421 N.W. 41ST STREET
SUITE A-1
GAINESVILLE FL 32606-6669

EXAMINER
CHANG, C

ART UNIT	PAPER NUMBER
1625	3

DATE MAILED: 09/28/01

Pl ase find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/928,139

Applicant(s)

LANGSTON ET AL.

Examiner

Celia Chang

Art Unit

1625

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 10 August 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

Art Unit: 1625

DETAILED ACTION

1. This application is a continuation of SN 08/792,415. Claims 1-7 are in the case.
2. Claims 1 and 5 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the claims encompassed racemisation proceeds in favor of the threo diastereomer lacks antecedent basis and enabling description in the specification.

Removal of NEW MATTER is required. In re Russmussen 211 USPQ 325.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaflee J. Med. Chem. in view of Barry CA 119 or Miller CA 94 and US 4,254,261.

Determination of the scope and content of the prior art (MPEP §2141.01)

Shaflee et al. disclosed process of making single R,R-threo-methylphenidate (see abstract last three lines).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

Shaflee et al. Disclosed all the elements of the claims **except** that a further racemisation step was not included. Barry taught that in preparation of amino acid esters analogous to the claims, racemisation of such ester is achieved under acidic conditions (see acetic acid) and recycling through racemization of the other isomer would give more of the intended isomer (see Miller Ca94 and '261 col.1 line 64-66).

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art is deemed to be aware of all the pertinent art in the field. The above references placed the single enantiomer, process of making and alternative choices for increasing single isomeric form in the possession of artisan in the field. It would have been prima facie obvious to employ a conventional modification of Barry or Miller for the

Art Unit: 1625

conventional process of Shaflee **because** producing higher yield of a desirable single isomer is expected which are the attributes taught by prior art.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaflee J. Med. Chem. in view of Barry CA 119 or Miller CA 94 and US 4,254,261 further in view of Rometsch US 2,957,880.

The finding of prima facie obviousness of claims 1-3, and 6 over Shaflee J. Med. Chem. in view of Barry CA 119 or Miller CA 94 and US 4,254,261 as delineated supra in section 4 is also applicable here and incorporated by reference. The further limitation of claims 4-5 that the separation of enantiomers can be carried out before or after esterification process is also conventional as taught by Rometsch '880 wherein, racemic separation were made before or after the racemic separation (see examples 1-2, col. 3-4, col. 6, lines 30-38).

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shaflee J. Med. Chem. in view of Barry CA 119 or Miller CA 94 and US 4,254,261 further in view of Rometsch US 2,957,880 further in view of Jacques supplemented with Harris US 6,242,464.

The finding of prima facie obviousness of claims 1-3, and 6 over Shaflee J. Med. Chem. in view of Barry CA 119 or Miller CA 94 and US 4,254,261 as delineated supra in section 4 is also applicable here and incorporated by reference. The further limitation of claims 4-5 that the separation of enantiomers can be carried out before or after esterification process is also conventional as taught by Rometsch '880 wherein, racemic separation were made before or after the racemic separation (see examples 1-2, col. 3-4, col. 6, lines 30-38).

The continued purification of the product through resolution with a resolving agent which is conventional (see Jacques) and operable (see Harris) is considered prima facie modification of the obvious process of the base claim **because** purer compounds is desirable and resolving a desirable enantiomer to its pure form employing a chiral resolving agent well recognized in the art is routine laboratory procedure.

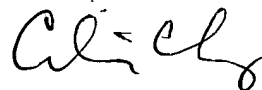
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 703-308-4702. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner can be reached by facsimile at (703) 308-7922 with courtesy voice message supra.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

CCPC/Chang

Sept. 26, 2001


CEILA CHANG
PRIMARY EXAMINER
GROUP 1200-1625